IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

KB PARTNERS I, L.P., Individually and on Behalf of All Others Similarly Situated,
Plaintiff,

-vs-

Case No. A-11-CA-1034-SS

PAIN THERAPEUTICS, INC., REMI BARBIER, NADAV FRIEDMANN, and PETER RODDY,
Defendants.

ORDER

BE IT REMEMBERED on this day the Court reviewed the file in the above-styled cause, and specifically Defendants Pain Therapeutics, Inc., Remi Barbier, Nadav Friedmann, and Peter Roddy's Motion to Dismiss the Third Amended Complaint [#231] and Memorandum of Law in Support [#231-1], Plaintiff KB Partners I, L.P.'s Opposition [#234] thereto, and Defendants' Reply [#236] in support. Having reviewed the documents, the governing law, and the file as a whole, the Court now enters the following opinion and orders.

Background

This is a longstanding securities fraud class action brought by Lead Plaintiff KB Partners I, L.P. (Plaintiff), an investment firm, against Defendant Pain Therapeutics, Inc. (PTI), a biopharmaceutical development company based in Austin, Texas, and Defendants Remi Barbier, Nadav Friedmann, and Peter Roddy, PTI's Chief Executive Officer, Chief Operating Officer, and Chief Financial Officer, respectively. Plaintiff alleges Defendants intentionally misled their shareholders regarding the U.S. Food and Drug Administration (FDA) approval process for Remoxy,

PTI's controlled-release and purportedly abuse-resistant form of the opioid painkiller oxycodone. Specifically, Plaintiff claims after the FDA rejected PTI's first New Drug Application (NDA) for Remoxy, PTI concealed the nature and extent of the problems with Remoxy from the public, falsely led investors to believe the FDA would approve a resubmitted NDA, and did so while lining its own pockets, rewarding the individual Defendants with unjustifiable compensation packages it asked the shareholders to approve.

The procedural posture of this case is unusual: four years after filing, and having once proceeded through discovery and motions practice all the way to the morning of jury selection, this action has now returned to the pleadings stage. Following an opposed motion for continuance filed two days before trial was slated to begin, *see* Opposed Mot. Continue [#209], the Court vacated almost all of its interlocutory orders[1] and directed Plaintiff to file a Third Amended Complaint. *See* Order of July 7, 2015 [#222]. Plaintiff did so, and Defendants have now filed their inevitable motion to dismiss. Although the Court has recounted the facts of this case in detail on many occasions, we must begin again at the beginning: a summary of the facts, drawn from the Third Amended Complaint and recounted in the light most favorable to Plaintiff, follows.

A. The First Remoxy NDA

PTI began developing Remoxy in late 2004 in partnership with King Pharmaceuticals (King), which was later acquired by Pfizer, Inc. Third Am. Compl. [#229] ¶¶ 3, 6. Following several years of clinical testing, in mid-2008, PTI and King submitted the first Remoxy NDA to the FDA. *Id.* ¶¶ 29, 34. An NDA contains data from clinical trials, pre-clinical studies, and manufacturing

[1] The Court excepted its order certifying the class and its orders admitting attorneys *pro hac vice*. *See* Order of July 7, 2015 [#222].

information used by the FDA to evaluate the applicant drug's safety and efficacy. Each NDA contains a section on "[c]hemistry, manufacturing, and controls," also called the "CMC" section, that includes detailed data on the applicant drug's stability, or performance over its proposed shelf life. *Id.* ¶¶ 30, 31. One important component of stability analysis, dissolution testing, tests the rate at which the drug's active ingredient is released from the delivery capsule or tablet over time, and is meant to simulate what will happen in the human body when a person takes the drug. *Id.* ¶ 32.

The FDA rejected the first Remoxy NDA in December 2008, explaining its reasoning for the rejection in a "Complete Response Letter" (the First CRL) sent to PTI. *Id.* ¶ 34. Among the FDA's reasons for rejecting the NDA were problems with the stability data supplied in the CMC section. Specifically, the FDA stated Remoxy's dissolution specifications exceeded "the maximum allowable difference between the upper and lower specifications," ±10% from the mean of all batches. *Id.* In other words, the dissolution data showed the rate of release of Remoxy's active ingredient was too inconsistent from batch to batch to ensure Remoxy would perform as expected when administered.

PTI subsequently issued a press release informing its shareholders the FDA rejected the Remoxy NDA. *Id.* ¶ 35. In explaining why, PTI stated the FDA was requesting "additional 'non-clinical' data on Remoxy," but noted the FDA did not need any further clinical efficacy studies "prior to approval." *Id.* The press release provided no further details. *See id.*

Following the rejection, King took charge of the Remoxy FDA-approval process and assumed sole responsibility for resubmission of the NDA. *Id.* ¶ 36. Pursuant to its "Collaboration Agreement" with PTI, King periodically updated PTI on the resubmission process. *Id.* ¶ 36. Additionally, several committees comprised of King and PTI employees, including a "Joint Oversight Committee" (JOC), a "CMC Response Working Group," and a "Dissolution Working

Group" were "tasked with addressing the dissolution and stability issues raised in the First CRL" in preparation for the resubmission. *Id.* ¶ 39. The JOC was a creature of the Collaboration Agreement and was charged with "oversight of the Development plans and Manufacturing/CMC Plans [for Remoxy], including all related strategy and objectives, timelines and activities thereunder[.]" *Id.* ¶ 25. Barbier and Friedmann were JOC members, and Roddy, while not a member, attended JOC meetings. *Id.* ¶ 24.

On July 2, 2009, King met with the FDA concerning the resubmission. *Id.* ¶ 37. During the meeting, the FDA told King it was "required" to include "a minimum of 6 months of stability [data]" in the resubmitted NDA. *Id.* Pursuant to the Collaboration Agreement, King sent the minutes of the meeting to Barbier and Friedmann. *Id.* ¶ 38. On July 7, 2009, PTI issued a press release stating "[PTI] believes the rate-limiting step [concerning the resubmission] is the generation of six-month stability data, and no new clinical trials are required." *Id.*

By March 2010, King and PTI became aware Remoxy's dissolution variability, even using a new testing methodology selected by King, remained outside acceptable specifications. *Id.* ¶ 45. As such, King decided to add a three-month "curing" step to the Remoxy manufacturing process, meaning after creation and bottling, the drug product would be held for three months before stability testing would begin. *See id.* Addition of the three-month curing period meant the NDA could be resubmitted no earlier than December 2010, as it would take a minimum of nine months to generate six months of stability data on new batches of Remoxy. *See id.* ¶ 46.

Three of the fifteen "cured" batches once again failed dissolution testing. *Id.* ¶ 48. A decision was made—the complaint does not reveal by whom—to cure the three failed batches for an additional three months and test them again, for a total curing period of six months. *See id.* The

addition of this additional curing time meant if the NDA was resubmitted in December 2010, only three months of stability data would be available for the three batches cured for six months, although six months of stability data would be available for the remaining twelve batches cured for three months. *See id.* ¶¶ 48–49. At some point prior to filing the resubmission, "King sent [PTI] the results of [the] dissolution testing . . . and told [PTI] the Resubmission would contain a variable curing period." *Id.* ¶ 49. According to Plaintiff, PTI had access to the stability section of the NDA "as early as December 3, 2010," and to the full NDA "by December 22, 2010." *Id.* ¶ 50.

B. The Second Remoxy NDA

King resubmitted the NDA on December 23, 2010. *Id.* Four days later, PTI issued the following press release:

> King Pharmaceuticals, Inc. and Pain Therapeutics, Inc. today announced that King has resubmitted a New Drug Application for REMOXY to the U.S. Food and Drug Administration in response to a Complete Response letter received by Pain Therapeutics in December 2008.

Id. ¶ 57. On February 3, 2011, PTI filed its 2010 Form 10-K with the Securities and Exchange Commission (SEC), which generally described the Remoxy FDA-approval process to date and stated the FDA had requested, prior to the resubmission, "additional non-clinical data" on Remoxy. *Id.* ¶ 59.

On March 4, 2011, the FDA sent a "Discipline Review Letter" to King concerning the CMC section of the resubmitted Remoxy NDA. *Id.* ¶ 52. A discipline review letter conveys the FDA's preliminary thoughts on possible deficiencies in a section of the NDA under review.[2] In the

[2] The Court takes judicial notice of the FDA's published explanation of discipline review letters. *See* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: INFORMATION REQUEST & DISCIPLINE REVIEW LETTERS UNDER THE PRESCRIPTION DRUG USER FEE ACT 2–3 (Nov. 2001), http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm172134.pdf

Discipline Review Letter sent to King, the FDA expressed doubt concerning Remoxy's new stability data, directing King to "[r]emove the variable 'curing' period" and indicating that although a curing period could properly be part of a drug manufacturing process, "the fact that your proposed 'curing' period may be either 3 or 6 months is not an indication that you have developed a formulation/manufacturing process that consistently produces drug product meeting those attributes related to identity, strength, quality, purity, and potency." *Id.* ¶ 52. Friedmann and Barbier received a copy of the Discipline Review Letter on March 14, 2011. *See id.*

On April 6, 2011, Roddy made the following comments about Remoxy and the FDA-approval process during a Needham & Company healthcare conference:

> [W]e received the complete response from the FDA in December 2008. Again, no new clinical efficacy trials were required for approval, and no change to the formulation was required as well. But in particular, the FDA asked for additional stability data on REMOXY's novel formulation. That and other information was submitted to the FDA in December. Again the resubmission [was] accepted in January of this year.

Id. ¶ 60.

On April 27, 2011, PTI filed a Form 10-Q quarterly report with the SEC for the period ending March 31, 2011, which like the Form 10-K filed a few months prior, generally described the Remoxy FDA-approval process to date and stated the FDA had requested, prior to the resubmission, "additional non-clinical data" on Remoxy. *Id.* ¶ 61.

On May 3, 2011, Pfizer, which had by that time acquired King, made the following statement regarding the Remoxy NDA during a public conference call with investment analysts:

> At this time we are working to address a specific issue in the manufacturing section of the [Remoxy] application, as well as to understanding [sic] potential implications for FDA's recent classwide REMS [Risk Evaluation and Mitigation Strategy]

> announcement for extended release opioids. These issues could delay the timing of approval for the launch of Remoxy.

Id. ¶ 64. That same day, the value of PTI shares dropped by approximately 7%, from $9.56 per share to $8.86 per share. *Id.* ¶ 67.

A week after the Pfizer public conference call, Barbier spoke about Remoxy and the FDA-approval process during a Bank of America Merrill Lynch healthcare conference. *Id.* ¶ 68. Specifically, Barbier stated:

> The NDA was originally filed in June of 2008. We received a complete response letter in December of that year, we ha[d] to go back to [do] some more work as is often the case with these things. [. . .]
>
> We received from the FDA priority review and we're granted priority review almost immediately. We had [an] FDA advisory panel in November of 2008 during which 11 were in favor of approving Remoxy versus eight that were against. Why were the eight against? I don't know. It's almost like there is always someone against Christmas, I suppose.
>
> We did receive a complete response from the FDA in December of 2008. It wasn't the right answer, but it was an answer. Particularly they confirm[ed] that no new clinical efficacy work is necessary. But they did ask us for more detailed stability work, which was done in the interim between 2008 and 2010.

Id. ¶ 68. Discussing Pfizer's statement it was "working to address a specific issue in the manufacturing section" of the Remoxy NDA during the May 3, 2011 public conference call, Barbier continued:

> So what does it mean? First of all, I'm not the oracle for Pfizer. I'm not a spokesperson for Pfizer; they are a company, we are a company. So if there is a secret meaning in these words, I don't have it. But I've heard a lot of conspiracy theories behind this. I actually subscribe, I take this exactly as it is.
>
> First of all, I think it is extraordinary that the CEO of Pfizer during an earnings call would come up and talk about Remoxy, keep in mind this is a drug that five years ago people were still doubting whether it was a legitimate drug and whether there was room for Remoxy. Suddenly fast forward to today, you've got the CEO [of]

> arguably, one of the biggest pharmaceutical companies guiding on Remoxy. We like that, in fact, I think it is [an] extraordinarily positive signal.
>
> Furthermore in the Q&A session, I believe the CEO of Pfizer did affirm that it is not if Remoxy gets approved, but when Remoxy gets approved, again an affirmative action or sentence[.]

Id. ¶ 69.

On June 24, 2011, PTI announced its receipt of a second Complete Response Letter (the Second CRL) from the FDA rejecting the Remoxy NDA resubmission. *Id.* ¶ 71. The press release did not describe the Second CRL, stating only that "Pfizer is working to evaluate the issues described" therein. *Id.* ¶ 72. Following the announcement, PTI's share price plummeted by nearly 43%, closing at $5.30 per share that same day. *Id.* ¶ 73.

In the Second CRL, the FDA informed Pfizer Remoxy's "fundamental design" was "unacceptable as the product fails to provide consistent drug release performance[,]" a deficiency "highlighted by . . . application of a variable holding [curing] period, dependent on drug release performance, prior to final drug product release." *Id.* ¶ 71. On June 27, 2011, PTI disclosed the specific reasons for the second rejection to the public, informing investors the FDA:

> raised concerns related to, among other matters, the Chemistry, Manufacturing, and Controls section of the NDA for REMOXY. Certain drug lots showed inconsistent release performance during *in vitro* testing. It is not known at this time whether this is an artifact of the testing method or a manufacturing deficiency.
>
> Sufficient information does not yet exist to accurately assess the time required to resolve the concerns raised in the [Second CRL]. In the opinion of Pain Therapeutics, potential regulatory approval of REMOXY in the U.S. is unlikely to occur in less than one year, and could be delayed significantly longer than a year.

Id. ¶ 74. After the announcement, PTI shares declined once again by nearly 26%, closing at $3.93 per share on June 27, 2011. *Id.* ¶ 75.

To date, PTI has not resubmitted the Remoxy NDA, and in October 2014, Pfizer terminated its development of Remoxy and returned all development and commercial rights to PTI. *Id.* ¶ 79.

C. Procedural History

On June 3, 2013, the Court certified a class consisting of "[a]ll purchasers of the common stock of Pain Therapeutics, Inc. during the period from December 27, 2010 [through] June 26, 2011, both dates inclusive." Order of June 3, 2013 [#112] at 26. As previously noted, the case progressed through discovery and motions practice to the eve of trial, when the Court granted Defendants' opposed motion to continue and vacated all interlocutory orders previously entered, save the order certifying the class and orders admitting attorneys *pro hac vice*. *See* Order of July 7, 2015 [#222].

Plaintiff filed its Third Amended Complaint on July 27, 2015, alleging: (1) all Defendants violated § 10(b) of the Securities Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 by making false and misleading statements designed to artificially inflate the price of PTI stock; and (2) the three individual defendants violated § 20(a) of the Securities Exchange Act based upon their positions as controlling persons within PTI. *See* Third Am. Compl. [#229] ¶¶ 88–101. The instant motion to dismiss followed.

Analysis

I. Legal Standard

A. Motion to Dismiss—Rule 12(b)(6)

Federal Rule of Civil Procedure 8(a)(2) requires a complaint to contain "a short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2). A motion under Federal Rule of Civil Procedure 12(b)(6) asks a court to dismiss a complaint for "failure to state a claim upon which relief can be granted." FED. R. CIV. P. 12(b)(6). The plaintiff

must plead sufficient facts to state a claim for relief that is facially plausible. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 566 U.S. at 678. Although a plaintiff's factual allegations need not establish that the defendant is probably liable, they must establish more than a "sheer possibility" that a defendant has acted unlawfully. *Id.* Determining plausibility is a "context-specific task," and must be performed in light of a court's "judicial experience and common sense." *Id.* at 679.

In deciding a motion to dismiss under Rule 12(b)(6), a court generally accepts as true all factual allegations contained within the complaint. *Leatherman v. Tarrant Cnty. Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 164 (1993). However, a court is not bound to accept legal conclusions couched as factual allegations. *Papasan v. Allain*, 478 U.S. 265, 286 (1986). Although all reasonable inferences will be resolved in favor of the plaintiff, the plaintiff must plead "specific facts, not mere conclusory allegations." *Tuchman v. DSC Commc'ns Corp.*, 14 F.3d 1061, 1067 (5th Cir. 1994). In deciding a motion to dismiss, courts may consider the complaint, as well as other sources such as documents incorporated into the complaint by reference, and matters of which a court may take judicial notice. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

B. Securities Exchange Act § 10(b) Pleading Requirements

Section 10(b) of the Securities Exchange Act of 1934 empowers the SEC to promulgate rules to prevent manipulative or deceptive practices in the sale or purchase of securities. 15 U.S.C. § 78j(b). Under this grant of authority, the SEC issued Rule 10b-5, which makes it unlawful:

> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5.

The Fifth Circuit has held the elements of a claim under § 10(b) are: (1) a misrepresentation or omission; (2) of a material fact; (3) in connection with the purchase or sale of a security; (4) scienter by the defendant; (5) justifiable reliance by the plaintiff; (6) damages; and (7) proximate cause. *Rosenzweig v. Azurix Corp.*, 332 F.3d 854, 865 (5th Cir. 2003). To establish scienter, a plaintiff must show the defendant intended to deceive, defraud, or manipulate, or that the defendant acted with severe recklessness. *Lormand v. US Unwired, Inc.*, 565 F.3d 228, 251 (5th Cir. 2009). Severe recklessness is limited to "highly unreasonable omissions or misrepresentations" involving an "extreme departure from the standards of ordinary care." *Nathenson v. Zonagen, Inc.*, 267 F.3d 400, 408 (5th Cir. 2001).

Both Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act (PSLRA) impose a heightened pleading requirement on § 10(b) claims. FED. R. CIV. P. 9(b); 15

U.S.C. § 78u-4(b). Rule 9(b) requires plaintiffs alleging fraud or mistake to "state with particularity the circumstances constituting fraud or mistake." FED. R. CIV. P. 9(b). In order to avoid dismissal under Rule 9(b) for lack of particularity, the Fifth Circuit has held a plaintiff must:

(1) specify each statement alleged to have been misleading, i.e., contended to be fraudulent;

(2) identify the speaker;

(3) state where and when the statement was made;

(4) plead with particularity the contents of the false representations;

(5) plead with particularity what the person making the misrepresentation obtained thereby; and

(6) explain the reason or reasons why the statement is misleading, i.e., why the statement is fraudulent.

Rosenzweig, 332 F.3d at 866.

The PSLRA dictates a more rigorous pleading standard for private securities fraud actions in two ways. First, in any such action alleging the defendant made an untrue statement of material fact or a misleading omission:

> [T]he complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.

15 U.S.C. § 78u-4(b). Second, for claims under which the plaintiff must prove a particular state of mind to recover:

> [T]he complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a *strong inference* that the defendant acted with the required state of mind.

Id. (emphasis added). Based on the elements of a § 10(b) claim described above, it is clear that § 10(b) claims are subject to both of these requirements of the PSLRA.

C. "Strong Inference" of Scienter Requirement

The United States Supreme Court has outlined a framework for courts to use in analyzing motions to dismiss § 10(b) complaints for failing to establish a "strong inference" of scienter. First, as in any other motion to dismiss, the court accepts all factual allegations in the complaint as true. Second, the court considers the entire complaint, other sources typically examined in a 12(b)(6) motion, sources incorporated by reference into the complaint, and matters of which a court may take judicial notice. Third, in determining whether the pleaded facts give rise to a "strong" inference of scienter, as required by the PSLRA, a court should consider all of the facts alleged, taken collectively, and should also take into account plausible opposing inferences. *Tellabs*, 551 U.S. at 322–23. The inference need not be irrefutable, nor even the most compelling of all competing inferences, but must be strong in light of other inferences. *Id.* at 324. Ultimately, a complaint will only survive if "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.*

II. Application

Defendants argue Plaintiff's complaint must be dismissed because (1) the three omissions Plaintiff describes are immaterial as a matter of law; (2) even if the omissions are material, the allegedly misleading statements Plaintiff identifies are forward-looking statements and true descriptions of historical facts, which are not actionable under the PSLRA's "safe harbor"; (3) even if the statements are actionable, Plaintiff has failed to articulate a viable theory of loss causation; and (4) none of Plaintiff's allegations support the "strong inference" of scienter required by the PSLRA.

As set forth below, the Court does not agree with Defendants, and finds Plaintiff's claims may proceed.

A. Materiality of the Omissions

The Third Amended Complaint alleges that following the resubmission of the Remoxy NDA on December 23, 2010, Defendants made misleading statements to shareholders by omitting three pieces of information: first, that the results of the dissolution testing conducted on Remoxy in preparation for the resubmission showed Remoxy remained unstable; second, that King added an "unprecedented three or six month variable 'curing' period to its proposed manufacturing process" for Remoxy; and third, that "as a result of the variable curing period," the resubmission "did not have the six months of stability data that the FDA had explicitly requested." Third Am. Compl. [#229] ¶ 4. Plaintiffs claim these pieces of information were "material risks to the approvability of Remoxy, which Defendants were duty bound to disclose." *Id.*

"A statement or omitted fact is 'material' if there is a substantial likelihood that a reasonable investor would consider the information important in making a decision to invest." *R & W Tech. Servs. Ltd. v. Commodity Futures Trading Comm'n*, 205 F.3d 165, 169 (5th Cir. 2000). Stated differently, materiality is the substantial likelihood a statement or omission "would have been viewed by the reasonable investor as having altered the total mix of information made available." *ABC Arbitrage Plaintiffs Grp. v. Tchuruk*, 291 F.3d 336, 359 (5th Cir. 2002) (internal quotations and citations omitted). Materiality is a mixed question of law and fact. *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 450 (1976) ("The determination requires delicate assessments of the inferences a 'reasonable shareholder' would draw from a given set of facts and the significance of those inferences to him, and these assessments are peculiarly ones for the trier of fact."); *United States v.*

Peterson, 101 F.3d 375, 380 (5th Cir. 1996) ("Because materiality is a mixed question of law and fact, it is usually left for the jury."). At the same time, "a court can determine statements to be immaterial as a matter of law on a motion to dismiss." *ABC Arbitrage*, 291 F.3d at 359.

The Court finds none of the three omissions Plaintiff alleges are immaterial as a matter of law. Following the FDA's rejection of the first Remoxy NDA, PTI issued its July 7, 2009 press release stating "[PTI] believes the rate-limiting step [concerning the resubmission] is the generation of six-month stability data, and no new clinical trials are required." Third Am. Compl. [#229] ¶ 38. PTI released information indicating the generation of additional stability data was material to the success of the resubmission; thus, a reasonable investor might well consider the information that (1) new test results showed Remoxy remained unstable, (2) King retained the three- or six-month variable curing period despite the FDA's admonishment to "[r]emove the variable 'curing' period" in its Discipline Review Letter, and (3) several of the tested batches did not include the six months of stability data requested by the FDA[3] important in making a decision to invest. "The omission of a known risk, its probability of materialization, and its anticipated magnitude, are usually material to any disclosure discussing the prospective result from a future course of action." *Lormand*, 565 F.3d at 248 (citations omitted).

[3] The Court notes Plaintiff's formulation of the third omission may itself be somewhat misleading. Twelve of the fifteen batches of Remoxy tested in preparation for the resubmission *did* include six months of stability data; only the three failed batches cured for a total of six months did not. PTI's omission, stated accurately, was not that "the resubmitted Remoxy NDA did not have the six months of stability data that the FDA had explicitly required," but that while twelve batches of Remoxy had six months of stability data, three batches had only three months of stability data. *See* Third Am. Compl. [#229] ¶ 4. It is not clear from the present record whether the FDA's directive King was "required" to include "a minimum of 6 months of stability data" meant that six months of stability data was required for all batches tested, or that six months of stability data was required for at least some of the batches tested. In any event, that question is inappropriate for resolution at the motion to dismiss stage. PTI was not required, of course, to disclose any information to the public in an overstated or inaccurate manner.

Further, "under Rule 10b-5, a duty to speak the full truth arises when a defendant undertakes a duty to say anything. Although such a defendant is under no duty to disclose every fact or assumption underlying a prediction, he must disclose material, firm-specific adverse facts that affect the validity or plausibility of that prediction." *Id.* at 249 (quoting *Rubinstein v. Collins*, 20 F.3d 160, 170 (5th Cir. 1994)). Simply stated, "companies can control what they have to disclose under [§ 10(b) and Rule 10b-5] by controlling what they say to the market." *Matrixx Initiatives v. Siracusano*, 563 U.S. 27, 131 S. Ct. 1309, 1322 (2011). Here, Defendants chose to tell the market the "rate-limiting step" in the resubmission process was "the generation of six-month stability data." As such, Defendants obligated themselves to "speak the full truth" regarding Remoxy's stability as the resubmission process unfolded.

While the trier of fact may well determine one or all of these omissions immaterial, the Court cannot say at this stage of the proceedings that these three omissions are so obviously unimportant to a reasonable investor that they are immaterial as a matter of law. Defendants' first argument is therefore rejected.

B. Whether the Alleged Misstatements are Actionable

Defendants next claim the five[4] misstatements Plaintiff alleges are not actionable as a matter of law because all are either "expressions of (true) historical fact, permissible corporate puffery, opinion, [or] forward-looking statements protected by the safe harbor provision of the PSLRA." Mem. Mot. Dismiss [#231-1]. "Forward-looking statements," according to the PSLRA, may include projections of revenues, plans for future operations relating to the issuer's products, and statements

[4] In its response to the motion to dismiss, Plaintiff clarified it does not allege the January 27, 2011 press release is misleading. *See* Resp. [#234] at 15 n.14.

regarding future economic performance, among other topics, *see* 15 U.S.C. § 78u-5(i)(1), and are immunized from liability if, among other circumstances, they are identified as forward-looking and accompanied by "meaningful cautionary statements." 15 U.S.C. §§ 78u-5(c)(1)(A)(i), (B); *Southland Sec. Corp. v. INSpire Ins. Solutions, Inc.*, 365 F.3d 353, 371–72 (5th Cir. 2004).

Plaintiff alleges five statements were misleading: (1) PTI's December 27, 2010 press release; (2) PTI's 2010 Form 10-K, filed February 3, 2011; (3) PTI's 2010 Form 10-Q, filed April 27, 2011; (4) Roddy's remarks at the Needham & Company healthcare conference on April 6, 2011; and (5) Barbier's statements during the May 11, 2010 Bank of America Merrill Lynch healthcare conference. The Court addresses each in turn.

i. The December 27, 2010 Press Release

First, Defendants argue the statement in the December 27, 2010 press release that King and PTI resubmitted the Remoxy NDA to the FDA "in response to [the First CRL]" was nothing more than "a clear and accurate historical fact." Mem. Mot. Dismiss [#231-1] at 13 (citing *In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 569 (S.D.N.Y. 2011)). According to Defendants, the word "response" is a "term of art" used by the FDA to describe when an NDA resubmission is ready for review. *Id.*

While it is a close question, the Court declines to hold this statement is not actionable as a matter of law. The ability of a statement to provide accurate information, rather than the statement's literal truth, is the benchmark by which statements to the market are measured in securities fraud cases. *Lormand*, 565 F.3d at 248. In light of PTI's previous disclosure to the market that additional stability data was required in the resubmission, the statement the resubmission was made "in response" to the First CRL could imply to a reasonable investor that the stability issues had been

adequately addressed. Rather than stating the resubmission was "in response to [the First CRL]," PTI could have issued a press release simply informing the market the second NDA had been submitted to the FDA. *See Sanofi-Aventis*, 774 F. Supp. 2d at 569 (holding the defendant's press release "announc[ing] the submission of" a clinical study report in the applicant drug's NDA which called the applicant drug's safety into question conveyed a clear and accurate historical fact). PTI chose to go one step further. This is enough to survive a motion to dismiss.

ii. The 2010 Form 10-K and Form 10-Q

Defendants next contend the statements made in PTI's 2010 Form 10-K and 2010 Form 10-Q were no more than accurate reporting of historical facts. Mem. Mot. Dismiss [#231-1] at 11, 14. The quotes from both documents cited by Plaintiffs in their complaint are nearly identical. The 10-K states:

> We and King jointly managed a Phase III clinical program and NDA submission for REMOXY. In mid-2008, the FDA accepted our NDA for REMOXY with Priority Review. In December 2008, we received from the FDA a Complete Response Letter for the NDA for REMOXY. In this Complete Response Letter, the FDA indicated additional non-clinical data is required to support the approval of REMOXY. The FDA has not requested or recommended additional clinical efficacy studies prior to approval. In 2009, King assumed sole responsibility for the regulatory approval of REMOXY. This shift of responsibility did not change any economic term of our strategic alliance with King. In December 2010, we and King announced that King had resubmitted the REMOXY NDA. In January 2011, we announced that the FDA had accepted King's resubmission of the REMOXY NDA.

Third Am. Compl. [#229] ¶ 59 (Form 10-K); *compare id. with id.* ¶ 61 (Form 10-Q).

The Court finds the statements "the FDA indicated additional non-clinical data is required to support the approval of REMOXY" and "[t]he FDA has not requested or recommended additional clinical efficacy studies prior to approval" in both the Form 10-K and 10-Q are actionable, as they paint an incomplete and misleading picture by failing to reference Remoxy's stability problems or

explain any of the steps taken to address the FDA's concerns. While it was literally true the FDA did not request additional clinical efficacy studies be performed, stability, not clinical efficacy, was Remoxy's problem. As such, these statements could be read as careful elisions reassuring the market not to worry and minimizing the risk posed by the FDA's request for additional non-clinical data by implying the real red flag would have been a request for further clinical efficacy studies.

With the exception of the statements regarding the "economic term[s]" of the PTI/King relationship, the Court finds the remaining statements from the Form 10-K and Form 10-Q quoted by Plaintiffs are non-actionable clear and accurate statements of historical fact. The statements regarding the "economic term[s]" of the PTI/King relationship have nothing to do with Plaintiffs' alleged omissions, would not lead a reasonable investor to believe Remoxy's stability problems had been resolved, and are therefore immaterial to the present action.

iii. Roddy's remarks at the Needham & Company healthcare conference

Defendants further claim Roddy's remarks made during the Needham & Company healthcare conference are not actionable because they were both accurate statements of historical fact and forward-looking statements protected by the PSLRA safe harbor. The Court disagrees with Defendants. As with the statements in the Form 10-K and Form 10-Q, Roddy's comments—that "no new clinical efficacy trials were required for [FDA] approval" and "no change to the formulation was required"—could be found to paint a misleading picture of the NDA resubmission process by drawing attention to the absence of clinical efficacy or formulation-related issues with Remoxy and away from the stability problems Defendants allegedly knew would result in rejection of the resubmitted NDA. Roddy, moreover, went even further; while he did acknowledge the FDA requested "additional stability data on Remoxy's novel formulation," he stated "[t]hat and other

information was submitted to the FDA in December." These statements could certainly lead a reasonable investor to believe that Remoxy's stability problems had been resolved prior to resubmission of the NDA, as they imply all of the additional data requested by the FDA had indeed been submitted. Plaintiffs, of course, allege this was not the case.

Somewhat confoundingly, and despite simultaneously taking the position Roddy's comments were statements of historical fact, Defendants further contend "[i]f Plaintiff is alleging" Roddy's statements "implicitly oversold Remoxy's approval prospects," those statements would be protected because they were forward-looking. The Court rejects this argument. Whether or not a statement is forward-looking is governed by the nature of the statement, not a litigant's allegations about the statement. Roddy's statements were not forward-looking; they described the materials given to the FDA in the December 2010 NDA resubmission. Thus, the statements do not fall within the PSLRA's safe harbor.

iv. Barbier's remarks during the Bank of America Merrill Lynch healthcare conference

Finally, Defendants claim Barbier's remarks during the Bank of America Merrill Lynch healthcare conference are not actionable because they are either accurate historical statements or mere corporate puffery. While the Court agrees some of Barbier's remarks were permissible puffery or a truthful recounting of history, other comments Barbier made were neither, and thus are actionable.

Discussing the First CRL, Barbier stated: "Particularly [the FDA] confirm[ed] that no new clinical efficacy work is necessary. But they did ask us for more detailed stability work, which was done in the interim between 2008 and 2010. [The] NDA w[as] resubmitted[.]" Third Am. Compl.

[#229] ¶ 68. These comments could be found misleading for the same reasons Roddy's comments and the statements in the Form 10-K and 10-Q could be found misleading. Stating the "detailed stability work" requested by the FDA "was done," without further elaboration, is incomplete, as it suggests Remoxy's stability issues were resolved before the resubmission.

Barbier then discussed Pfizer's remarks made during the public conference call that Pfizer was "working to address a specific issue in the manufacturing section" of the NDA that "could delay the time of approval or the launch of Remoxy." *See id.* ¶¶ 64, 69. Specifically, Barbier commented: "I believe the CEO of Pfizer did affirm that it is not if Remoxy gets approved, but when Remoxy gets approved, again an affirmative action or sentence on the of [sic] Remoxy." *Id.* ¶ 69. Defendant's characterization of these remarks as "cabined optimism" seems to the Court overly optimistic. Particularly in light of Remoxy's unresolved stability problems and PTI's choice to reveal a stability issue to the market, this statement goes well beyond mere corporate puffery and could certainly lead a reasonable investor to believe that any barriers to approval posed by Remoxy's stability problems had been overcome; "not if, but when" stops just shy of a rhetorical guarantee. Additionally, the Court rejects Defendants' contentions Barbier's comments are shielded by his prefatory disclaimer "I'm not the oracle for Pfizer" and because Barbier was recounting something the Pfizer CEO allegedly said. The PSLRA does not immunize finger-pointing. Barbier is accountable for the words that came out of his mouth.

The remainder of Barbier's comments, however, are not actionable. Comparing Remoxy to the Christmas holiday and referring to the relationship between Pfizer and Remoxy as "extraordinarily positive" are "generalized, positive statements about [Remoxy's] competitive strengths" which are not "specific enough to perpetrate a fraud on the market" and are therefore

immaterial. *Rosenzweig*, 332 F.3d at 869 (quoting *Raab v. Gen. Physics Corp.*, 4 F.3d 286, 290 (4th Cir. 1993)). Finally, Barbier's remaining statements describe the filing of the first NDA and Remoxy's receipt of priority review. Neither are relevant to stability, and both truthfully recount history; thus, they are not actionable.

The Court finds Plaintiffs have adequately alleged misleading statements made on each of the five occasions discussed above.

C. Scienter

The parties next dispute the sufficiency of Plaintiff's scienter allegations. In the Fifth Circuit, "[t]he required state of mind is an 'intent to deceive, manipulate, or defraud' or 'severe recklessness.'" *Indiana Elec. Workers Pension Trust Fund IBEW v. Shaw Grp., Inc.*, 537 F.3d 527, 533 (5th Cir. 2008) (quoting *Rosenzweig*, 332 F.3d at 866). "Thus, a securities fraud plaintiff must prove that the defendant either consciously misbehaved . . . or was so severely reckless that it demonstrates that the defendant must have been aware of the danger of misleading the investing public." *Plotkin v. IP Axess Inc.*, 407 F.3d 690, 697 (5th Cir. 2005); *see also Tellabs*, 551 U.S. at 319.

Scienter must be specifically pleaded for each defendant. *Southland*, 365 F.3d at 365 ("[T]he PSLRA requires the plaintiffs to distinguish among those they sue and enlighten *each defendant* as to his or her particular part in the alleged fraud."). While a corporate officer may not be held responsible for a corporate statement solely because he or she is an officer, a corporate statement may be charged to an officer if the plaintiff alleges the officer signed the document containing the statements or otherwise adequately alleges the officer's involvement in creating the document. *Id.* Additionally, "the corporation itself may be treated as making press releases and public statements

issued by authorized officers on its behalf, and statements made by its authorized officers to further the interests of the corporation." *Id.* Consequently, in the Fifth Circuit, a court need look only to "'the allegations claimed to adequately show [scienter] on the part of the [named officers]' to determine whether the complaint sufficiently pleads scienter." *Indiana Elec. Workers*, 537 F.3d at 533–34 (quoting *Southland*, 365 F.3d at 367).

The Court finds Plaintiff's allegations concerning the individual Defendants support an "inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324. First, the Third Amended Complaint locates each of the individual Defendants in conversations with King/Pfizer employees regarding Remoxy's stability problems. The complaint alleges Barbier and Friedmann discussed Remoxy's stability issues during meetings of the JOC, which the Collaboration Agreement charges with "oversight of the Development [P]lans and Manufacturing/CMC Plans [for Remoxy], including all related strategy and objectives, timelines and activities thereunder[.]" Third Am. Compl. [#229] ¶ 25. Plaintiff alleges Roddy, "while not a member, attended JOC meetings." *Id.* ¶ 24. Further, Plaintiff claims during an April 6, 2010 JOC meeting, Michael Zamloot, PTI's Vice President of Technical Operations and "a technical expert on the Remoxy formulation," participated, and explained to all three of the individual Defendants that the new stability testing modality selected by King in the wake of the First CRL had not improved Remoxy's stability testing results. *See id.* ¶ 82.

Second, and relatedly, the complaint alleges that following the First CRL, Barbier, Friedmann and Roddy "took the lead role on behalf of [PTI] to stay apprised of the resubmission process for Remoxy . . . through formal and informal meetings with King personnel." *Id.* ¶ 36. The Third Amended Complaint alleges numerous examples of the individual Defendants' communications with

King/Pfizer employees in this role. According to Plaintiff, after King's July 2009 meeting with the FDA regarding the resubmission—during which the FDA told King "a minimum of 6 months of stability [data] is required"—King sent the meeting minutes to Barbier and Friedmann, which precipitated the joint PTI/King press release identifying the "rate-limiting step" in the Remoxy resubmission as "the generation of six-month stability data." *Id.* ¶ 38. Plaintiff claims Barbier and King's CEO, Brian Markinson, were "close" and "had frequent communications . . . throughout the resubmission process and Class Period." *Id.* ¶ 41. Further, Plaintiff states its Confidential Witness 1 (CW1), the Director of Finance at PTI from 2000 until September 2011, will testify Barbier met with King representatives regarding the resubmission and began drafting all of PTI's press releases after receipt of the First CRL in 2009. *Id.* ¶¶ 55, 83(d). Finally, the Third Amended Complaint alleges Grant Schoenhard, PTI's Chief Scientific Officer who "work[ed] intimately with King" on the resubmission, funneled information regarding the resubmission to Barbier. *Id.* ¶ 83(c).

Additionally, Plaintiff contends that no later than March 14, 2011, Barbier and Friedman received a copy of the FDA's Discipline Review Letter, which strongly criticized the variable curing period and directed King to "[r]emove" it. *Id.* ¶ 52. The Third Amended Complaint alleges the individual Defendants "received updates confirming that King had not resolved the variable curing problem" in the subsequent months, and then on May 18, 2011, received an email "confirming that King would not respond to the variable curing issue" raised in the Discipline Review Letter and noting King "understood the implications" of its failure to do so. *Id.*

Third, with respect to Barbier and Roddy, their own statements corroborate Plaintiff's allegation they knew about the specific stability problems Remoxy faced as the resubmission process unfolded. During the Bank of America Merrill Lynch healthcare conference, Barbier stated the FDA

"did ask us for more detailed stability work, which was done in the interim between 2008 and 2010." *Id.* ¶ 68. Similarly, at the Needham & Company healthcare conference, Roddy stated "the FDA asked for additional stability data on Remoxy's novel formulation. That and other information was submitted to the FDA in December." *Id.* ¶ 60. These comments indicate Barbier and Roddy were, at the very least, aware of Remoxy's stability problems during the resubmission process.

Given all of the above, the Court finds Plaintiff has adequately alleged facts which support an inference the individual Defendants acted with scienter, either because they were (1) fully aware of the nature and extent of Remoxy's stability problems yet still chose to make misleading public statements, or (2) severely reckless in making those statements without knowing whether the problems that led the FDA to reject the first Remoxy NDA had been resolved. It is also possible that the individual Defendants were unaware how deep Remoxy's stability problems ran despite all of the meetings with and emails from King personnel regarding the resubmission. Indeed, Defendants argue the importance of Remoxy to PTI's survival makes it implausible Defendants would encourage King to resubmit an NDA doomed to fail. *See* Mem. Mot. Dismiss [#231-1] at 26. While Defendants' point is well taken, the Court finds Plaintiff's preferred inference is "cogent and at least as compelling" as Defendants' alternate narrative. Plaintiff has adequately alleged scienter.

D. Loss Causation

Finally, Defendants argue Plaintiff has failed to plead loss causation. Under the PLSRA, a private plaintiff who claims securities fraud ultimately has the burden of proving the defendant's fraudulent act or omission caused the loss for which the plaintiff seeks to recover. 15 U.S.C. § 78u-4(b)(4). At the pleadings stage, loss causation allegations must be specific enough to show the alleged misrepresentation actually caused the loss; merely "touching upon" the loss is insufficient.

Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 343 (2005). Allegations the price of a security was inflated on the date of purchase because of the misrepresentation are not enough. *Id.* at 338.

Here, the Third Amended Complaint adequately pleads loss causation, as it alleges both an inflated purchase price and a series of subsequent price drops as information regarding the problems with the Remoxy resubmission leaked into the market. *See* Third Am. Compl. [#229] ¶¶ 67, 73, 75–78. Arguing otherwise, Defendants cite to the Southern District of New York's opinion in *Fort Worth Employers' Retirement Fund v. Biovail Corp.*, 615 F. Supp. 2d 218 (S.D.N.Y. 2009). *Fort Worth* is readily distinguishable. The *Fort Worth* plaintiff's theory was that the defendant drug company committed fraud by failing to inform investors its NDA was unlikely to be approved by the FDA because it relied on a "multiple-dose" bioequivalence study rather than a "single-dose" bioequivalence study. *Id.* at 229. The court found the complaint failed to plead loss causation because it neither alleged a corrective disclosure that revealed the truth behind a prior misrepresentation nor otherwise tied the decline in the defendant's stock price to fraud. *Id.*

Unlike in the present case, the only "corrective disclosure" the *Fort Worth* plaintiff alleged was the announcement the defendant's drug had not been approved, which made no reference to the bioequivalence study the plaintiff claimed caused the denial. *Id.* at 223–24. Here, two of Plaintiff's alleged corrective disclosures are specifically directed to Remoxy's stability problems: first, Pfizer's conference-call announcement that "a specific issue in the manufacturing section" of the Remoxy NDA might delay FDA approval, and second, PTI's press release, released after the FDA rejected Remoxy's resubmitted NDA, which indicated the Second CRL "raised concerns related to, among other matters, the Chemistry, Manufacturing, and Controls section of the NDA" and revealed that "[c]ertain [Remoxy] lots showed inconsistent performance during in vitro testing." *Id.* ¶¶ 64, 74.

Further, the Court finds the announcement of the Second CRL, despite its lack of reference to Remoxy's stability issues, may be a relevant loss-inducing event because it may fairly be characterized as the materialization of a known risk—namely, the risk the resubmitted NDA would be rejected given Remoxy's persistent stability problems. Plaintiff alleges the FDA explicitly warned Defendants their stability data was problematic in the First CRL, the July 2009 meeting, and the Discipline Review Letter. This directly contrasts with the situation in *Fort Worth*, where the plaintiff failed to allege the defendant had any warning its NDA was insufficiently supported. *See id.* at 228 ("There is not a single allegation in the Amended Complaint that the FDA ever explicitly warned defendants that they were proceeding with an insufficiently supported application. . . . [T]he agency never once mentioned the inappropriateness of relying on multiple-dose studies in support of NDAs.").

In sum, as Plaintiff's alleged disclosures "reflect part of the 'relevant truth'—the truth obscured by the [allegedly] fraudulent statements"—they sufficiently allege loss causation in compliance with the Federal Rules. *Alaska Elec. Pension Fund v. Flowserve Corp.*, 572 F.3d 221, 230 (5th Cir. 1990); *see Dura*, 544 U.S. at 347 (finding complaint failed to adequately plead loss causation where plaintiffs "fail[ed] to claim that Dura's share price fell significantly after the truth became known"). Defendants' argument to the contrary is rejected.

Conclusion

Taking the allegations of the Third Amended Complaint as true, the Court finds Plaintiffs have adequately pled their causes of action for securities fraud in accordance with the PSLRA and the Federal Rules of Civil Procedure. Defendants' motion to dismiss must therefore be denied.

Accordingly:

IT IS ORDERED that Defendants Pain Therapeutics, Inc., Remi Barbier, Nadav Friedmann, and Peter Roddy's Motion to Dismiss the Third Amended Complaint [#231] is DENIED.

SIGNED this the 30th day of November 2015.

SAM SPARKS
UNITED STATES DISTRICT JUDGE